

Your Child's First Vaccines

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

The vaccines covered on this statement are those most likely to be given during the same visits during infancy and early childhood. Other vaccines (including measles, mumps, and rubella; varicella; rotavirus; influenza; and hepatitis A) are also routinely recommended during the first five years of life.

Your child will get these vaccines today:

DTaP Hib Hepatitis B Polio PCV13

(Provider: Check appropriate boxes.)

1 Why get vaccinated?

Vaccine-preventable diseases are much less common than they used to be, thanks to vaccination. But they have not gone away. Outbreaks of some of these diseases still occur across the United States. **When fewer babies get vaccinated, more babies get sick.**

7 childhood diseases that can be prevented by vaccines:

1. Diphtheria (the 'D' in DTaP vaccine)

- **Signs and symptoms** include a thick coating in the back of the throat that can make it hard to breathe.
- **Diphtheria can lead to** breathing problems, paralysis and heart failure.
 - About 15,000 people died each year in the U.S. from diphtheria before there was a vaccine.

2. Tetanus (the 'T' in DTaP vaccine; also known as Lockjaw)

- **Signs and symptoms** include painful tightening of the muscles, usually all over the body.
- **Tetanus can lead to** stiffness of the jaw that can make it difficult to open the mouth or swallow.
 - Tetanus kills about 1 person out of every 10 who get it.

3. Pertussis (the 'P' in DTaP vaccine, also known as Whooping Cough)

- **Signs and symptoms** include violent coughing spells that can make it hard for a baby to eat, drink, or breathe. These spells can last for several weeks.
- **Pertussis can lead to** pneumonia, seizures, brain damage, or death. Pertussis can be very dangerous in infants.
 - Most pertussis deaths are in babies younger than 3 months of age.

4. Hib (*Haemophilus influenzae* type b)

- **Signs and symptoms** can include fever, headache, stiff neck, cough, and shortness of breath. There might not be any signs or symptoms in mild cases.
- **Hib can lead to** meningitis (infection of the brain and spinal cord coverings); pneumonia; infections of the ears, sinuses, blood, joints, bones, and covering of the heart; brain damage; severe swelling of the throat, making it hard to breathe; and deafness.
 - Children younger than 5 years of age are at greatest risk for Hib disease.

5. Hepatitis B

- **Signs and symptoms** include tiredness, diarrhea and vomiting, jaundice (yellow skin or eyes), and pain in muscles, joints and stomach. But usually there are no signs or symptoms at all.
- **Hepatitis B can lead to** liver damage, and liver cancer. Some people develop chronic (long term) hepatitis B infection. These people might not look or feel sick, but they can infect others.
 - Hepatitis B can cause liver damage and cancer in 1 child out of 4 who are chronically infected.

6. Polio

- **Signs and symptoms** can include flu-like illness, or there may be no signs or symptoms at all.
- **Polio can lead to** permanent paralysis (can't move an arm or leg, or sometimes can't breathe) and death.
 - In the 1950s, polio paralyzed more than 15,000 people every year in the U.S.



U.S. Department of
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7. Pneumococcal Disease

- **Signs and symptoms** include fever, chills, cough, and chest pain. In infants, symptoms can also include meningitis, seizures, and sometimes rash.
- **Pneumococcal disease can lead to meningitis** (infection of the brain and spinal cord coverings); infections of the ears, sinuses and blood; pneumonia; deafness; and brain damage.
 - About 1 out of 15 children who get pneumococcal meningitis will die from the infection.

Children usually catch these diseases from other children or adults, who might not even know they are infected. A mother infected with hepatitis B can infect her baby at birth. Tetanus enters the body through a cut or wound; it is not spread from person to person.

Vaccines that protect your baby from these seven diseases:

Vaccine	Number of doses	Recommended ages	Other information
DTaP (Diphtheria, Tetanus, Pertussis)	5	2 months, 4 months, 6 months, 15-18 months, 4-6 years	Some children get a vaccine called DT (Diphtheria & Tetanus) instead of DTaP.
Hepatitis B	3	Birth, 1-2 months, 6-18 months	
Polio	4	2 months, 4 months, 6-18 months, 4-6 years	An additional dose of polio vaccine may be recommended for travel to certain countries.
Hib (<i>Haemophilus influenzae</i> type b)	3 or 4	2 months, 4 months, (6 months), 12-15 months	There are several Hib vaccines. With one of them the 6-month dose is not needed.
Pneumococcal (PCV13)	4	2 months, 4 months, 6 months, 12-15 months	Older children with certain health conditions also need this vaccine.

Your healthcare provider might offer some of these vaccines as **combination vaccines**—several vaccines given in the same shot. Combination vaccines are as safe and effective as the individual vaccines, and can mean fewer shots for your baby.

2

Some children should not get certain vaccines

Most children can safely get all of these vaccines. But there are some exceptions:

- A child who has a mild cold or other illness on the day vaccinations are scheduled may be vaccinated. A child who is moderately or severely ill on the day of vaccinations might be asked to come back for them at a later date.
- Any child who had a life-threatening allergic reaction after getting a vaccine should not get another dose of that vaccine. **Tell the person giving the vaccines if your child has ever had a severe reaction after any vaccination.**
- A child who has a severe (life-threatening) allergy to a substance should not get a vaccine that contains that substance. **Tell the person giving your child the vaccines if your child has any severe allergies that you are aware of.**

Talk to your doctor before your child gets:

- **DTaP vaccine**, if your child ever had any of these reactions after a previous dose of DTaP:
 - A brain or nervous system disease within 7 days,
 - Non-stop crying for 3 hours or more,
 - A seizure or collapse,
 - A fever of over 105°F.
- **PCV13 vaccine**, if your child ever had a severe reaction after a dose of DTaP (or other vaccine containing diphtheria toxoid), or after a dose of PCV7, an earlier pneumococcal vaccine.

3

Risks of a Vaccine Reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Most vaccine reactions are not serious: tenderness, redness, or swelling where the shot was given; or a mild fever. These happen soon after the shot is given and go away within a day or two. They happen with up to about half of vaccinations, depending on the vaccine.

Serious reactions are also possible but are rare.

Polio, Hepatitis B and Hib Vaccines have been associated only with mild reactions.

DTaP and **Pneumococcal** vaccines have also been associated with other problems:

DTaP Vaccine

- **Mild Problems:** Fussiness (up to 1 child in 3); tiredness or loss of appetite (up to 1 child in 10); vomiting (up to 1 child in 50); swelling of the entire arm or leg for 1-7 days (up to 1 child in 30)—usually after the 4th or 5th dose.
- **Moderate Problems:** Seizure (1 child in 14,000); non-stop crying for 3 hours or longer (up to 1 child in 1,000); fever over 105°F (1 child in 16,000).
- **Serious problems:** Long term seizures, coma, lowered consciousness, and permanent brain damage have been reported following DTaP vaccination. These reports are extremely rare.

Pneumococcal Vaccine

- **Mild Problems:** Drowsiness or temporary loss of appetite (about 1 child in 2 or 3); fussiness (about 8 children in 10).
- **Moderate Problems:** Fever over 102.2°F (about 1 child in 20).

After any vaccine:

Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

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What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, and difficulty breathing. In infants, signs of an allergic reaction might also include fever, sleepiness, and disinterest in eating. In older children signs might include a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

5

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

6

How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)**
 - Visit CDC's website at www.cdc.gov/vaccines or www.cdc.gov/hepatitis

Vaccine Information Statement **Multi Pediatric Vaccines**

11/05/2015

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

DTaP Vaccine

What You Need to Know

(Diphtheria,
Tetanus and
Pertussis)

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1 Why get vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

DIPHTHERIA causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

TETANUS (Lockjaw) causes painful tightening of the muscles, usually all over the body.

- It can lead to “locking” of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in up to 2 out of 10 cases.

PERTUSSIS (Whooping Cough) causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These spells can last for weeks.

- It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (DTaP) can help prevent these diseases. Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

2 Who should get DTaP vaccine and when?

Children should get 5 doses of DTaP vaccine, one dose at each of the following ages:

- 2 months
- 4 months
- 6 months
- 15–18 months
- 4–6 years

DTaP may be given at the same time as other vaccines.

3 Some children should not get DTaP vaccine or should wait

- Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.
- Any child who had a life-threatening allergic reaction after a dose of DTaP should not get another dose.
- Any child who suffered a brain or nervous system disease within 7 days after a dose of DTaP should not get another dose.
- Talk with your doctor if your child:
 - had a seizure or collapsed after a dose of DTaP,
 - cried non-stop for 3 hours or more after a dose of DTaP,
 - had a fever over 105°F after a dose of DTaP.

Ask your doctor for more information. Some of these children should not get another dose of pertussis vaccine, but may get a vaccine without pertussis, called **DT**.

4 Older children and adults

DTaP is not licensed for adolescents, adults, or children 7 years of age and older.

But older people still need protection. A vaccine called **Tdap** is similar to DTaP. A single dose of Tdap is recommended for people 11 through 64 years of age. Another vaccine, called **Td**, protects against tetanus and diphtheria, but not pertussis. It is recommended every 10 years. There are separate Vaccine Information Statements for these vaccines.



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5**What are the risks from DTaP vaccine?**

Getting diphtheria, tetanus, or pertussis disease is much riskier than getting DTaP vaccine.

However, a vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of DTaP vaccine causing serious harm, or death, is extremely small.

Mild problems (common)

- Fever (up to about 1 child in 4)
- Redness or swelling where the shot was given (up to about 1 child in 4)
- Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses. Sometimes the 4th or 5th dose of DTaP vaccine is followed by swelling of the entire arm or leg in which the shot was given, lasting 1–7 days (up to about 1 child in 30).

Other mild problems include:

- Fussiness (up to about 1 child in 3)
- Tiredness or poor appetite (up to about 1 child in 10)
- Vomiting (up to about 1 child in 50)

These problems generally occur 1–3 days after the shot.

Moderate problems (uncommon)

- Seizure (jerking or staring) (about 1 child out of 14,000)
- Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)
- High fever, over 105°F (about 1 child out of 16,000)

Severe problems (very rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after DTaP vaccine. These include:
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage.

These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures. You can reduce fever and pain by giving your child an *aspirin-free* pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

6**What if there is a serious reaction?****What should I look for?**

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

7**The National Vaccine Injury Compensation Program**

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

8**How can I learn more?**

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

**Vaccine Information Statement
DTaP Vaccine**

5/17/2007

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Office Use Only



Hepatitis A Vaccine

What You Need to Know

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1 Why get vaccinated?

Hepatitis A is a serious liver disease. It is caused by the hepatitis A virus (HAV). HAV is spread from person to person through contact with the feces (stool) of people who are infected, which can easily happen if someone does not wash his or her hands properly. You can also get hepatitis A from food, water, or objects contaminated with HAV.

Symptoms of hepatitis A can include:

- fever, fatigue, loss of appetite, nausea, vomiting, and/or joint pain
- severe stomach pains and diarrhea (mainly in children), or
- jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements).

These symptoms usually appear 2 to 6 weeks after exposure and usually last less than 2 months, although some people can be ill for as long as 6 months. If you have hepatitis A you may be too ill to work.

Children often do not have symptoms, but most adults do. You can spread HAV without having symptoms.

Hepatitis A can cause liver failure and death, although this is rare and occurs more commonly in persons 50 years of age or older and persons with other liver diseases, such as hepatitis B or C.

Hepatitis A vaccine can prevent hepatitis A. Hepatitis A vaccines were recommended in the United States beginning in 1996. Since then, the number of cases reported each year in the U.S. has dropped from around 31,000 cases to fewer than 1,500 cases.

2 Hepatitis A vaccine

Hepatitis A vaccine is an inactivated (killed) vaccine. You will need **2 doses** for long-lasting protection. These doses should be given at least 6 months apart.

Children are routinely vaccinated between their first and second birthdays (12 through 23 months of age). Older children and adolescents can get the vaccine after 23 months. Adults who have not been vaccinated previously and want to be protected against hepatitis A can also get the vaccine.

You should get hepatitis A vaccine if you:

- are traveling to countries where hepatitis A is common,
- are a man who has sex with other men,
- use illegal drugs,
- have a chronic liver disease such as hepatitis B or hepatitis C,
- are being treated with clotting-factor concentrates,
- work with hepatitis A-infected animals or in a hepatitis A research laboratory, or
- expect to have close personal contact with an international adoptee from a country where hepatitis A is common

Ask your healthcare provider if you want more information about any of these groups.

There are no known risks to getting hepatitis A vaccine at the same time as other vaccines.

3 Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.**
If you ever had a life-threatening allergic reaction after a dose of hepatitis A vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.
- **If you are not feeling well.**
If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get hepatitis A vaccine do not have any problems with it.

Minor problems following hepatitis A vaccine include:

- soreness or redness where the shot was given
- low-grade fever
- headache
- tiredness

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

Your doctor can tell you more about these reactions.

Other problems that could happen after this vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your provider if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer lasting than the more routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious problem?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your clinic.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement
Hepatitis A Vaccine

7/20/2016

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Hepatitis B Vaccine

What You Need to Know

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1 Why get vaccinated?

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus. Hepatitis B can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness.

Hepatitis B virus infection can be either acute or chronic.

Acute hepatitis B virus infection is a short-term illness that occurs within the first 6 months after someone is exposed to the hepatitis B virus. This can lead to:

- fever, fatigue, loss of appetite, nausea, and/or vomiting
- jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements)
- pain in muscles, joints, and stomach

Chronic hepatitis B virus infection is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to:

- liver damage (cirrhosis)
- liver cancer
- death

Chronically-infected people can spread hepatitis B virus to others, even if they do not feel or look sick themselves.

Up to 1.4 million people in the United States may have chronic hepatitis B infection. About 90% of infants who get hepatitis B become chronically infected and about 1 out of 4 of them dies.

Hepatitis B is spread when blood, semen, or other body fluid infected with the Hepatitis B virus enters the body of a person who is not infected. People can become infected with the virus through:

- Birth (a baby whose mother is infected can be infected at or after birth)
- Sharing items such as razors or toothbrushes with an infected person
- Contact with the blood or open sores of an infected person
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Exposure to blood from needlesticks or other sharp instruments

Each year about 2,000 people in the United States die from hepatitis B-related liver disease.

Hepatitis B vaccine can prevent hepatitis B and its consequences, including liver cancer and cirrhosis.

2 Hepatitis B vaccine

Hepatitis B vaccine is made from parts of the hepatitis B virus. It cannot cause hepatitis B infection. The vaccine is usually given as 3 or 4 shots over a 6-month period.

Infants should get their first dose of hepatitis B vaccine at birth and will usually complete the series at 6 months of age.

All **children and adolescents** younger than 19 years of age who have not yet gotten the vaccine should also be vaccinated.

Hepatitis B vaccine is recommended for unvaccinated **adults** who are at risk for hepatitis B virus infection, including:

- People whose sex partners have hepatitis B
- Sexually active persons who are not in a long-term monogamous relationship
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Men who have sexual contact with other men
- People who share needles, syringes, or other drug-injection equipment
- People who have household contact with someone infected with the hepatitis B virus
- Health care and public safety workers at risk for exposure to blood or body fluids
- Residents and staff of facilities for developmentally disabled persons
- Persons in correctional facilities
- Victims of sexual assault or abuse
- Travelers to regions with increased rates of hepatitis B
- People with chronic liver disease, kidney disease, HIV infection, or diabetes
- Anyone who wants to be protected from hepatitis B

There are no known risks to getting hepatitis B vaccine at the same time as other vaccines.



3**Some people should not get this vaccine**

Tell the person who is giving the vaccine:

- **If the person getting the vaccine has any severe, life-threatening allergies.**

If you ever had a life-threatening allergic reaction after a dose of hepatitis B vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.

- **If the person getting the vaccine is not feeling well.**

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4**Risks of a vaccine reaction**

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get hepatitis B vaccine do not have any problems with it.

Minor problems following hepatitis B vaccine include:

- soreness where the shot was given
- temperature of 99.9°F or higher

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

Your doctor can tell you more about these reactions.

Other problems that could happen after this vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than the more routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

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What should I look for?

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Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your clinic.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

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Vaccine Information Statement
Hepatitis B Vaccine

7/20/2016

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

Hib Vaccine

(*Haemophilus
Influenzae* Type b)

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What You Need to Know

1 Why get vaccinated?

Haemophilus influenzae type b (Hib) disease is a serious disease caused by bacteria. It usually affects children under 5 years old. It can also affect adults with certain medical conditions.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person. If the germs stay in the child's nose and throat, the child probably will not get sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems. This is called invasive Hib disease.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the lining of the brain and spinal cord. It can lead to brain damage and deafness. Hib disease can also cause:

- pneumonia
- severe swelling in the throat, making it hard to breathe
- infections of the blood, joints, bones, and covering of the heart
- death

Before Hib vaccine, about 20,000 children in the United States under 5 years old got Hib disease each year, and about 3% - 6% of them died.

Hib vaccine can prevent Hib disease. Since use of Hib vaccine began, the number of cases of invasive Hib disease has decreased by more than 99%. Many more children would get Hib disease if we stopped vaccinating.

2 Hib vaccine

Several different brands of Hib vaccine are available. Your child will receive either 3 or 4 doses, depending on which vaccine is used.

Doses of Hib vaccine are usually recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed, depending on brand of vaccine)
- Final/Booster Dose: 12–15 months of age

Hib vaccine may be given at the same time as other vaccines.

Hib vaccine may be given as part of a combination vaccine. Combination vaccines are made when two or more types of vaccine are combined together into a single shot, so that one vaccination can protect against more than one disease.

Children over 5 years old and adults usually do not need Hib vaccine. But it may be recommended for older children or adults with asplenia or sickle cell disease, before surgery to remove the spleen, or following a bone marrow transplant. It may also be recommended for people 5 to 18 years old with HIV. Ask your doctor for details.

Your doctor or the person giving you the vaccine can give you more information.



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3**Some people should not get this vaccine**

Hib vaccine should not be given to infants younger than 6 weeks of age.

A person who has ever had a life-threatening allergic reaction after a previous dose of Hib vaccine, OR has a severe allergy to any part of this vaccine, should not get Hib vaccine. *Tell the person giving the vaccine about any severe allergies.*

People who are mildly ill can get Hib vaccine. People who are moderately or severely ill should probably wait until they recover. Talk to your healthcare provider if the person getting the vaccine isn't feeling well on the day the shot is scheduled.

4**Risks of a vaccine reaction**

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare.

Most people who get Hib vaccine do not have any problems with it.

Mild Problems following Hib vaccine:

- redness, warmth, or swelling where the shot was given
- fever

These problems are uncommon. If they occur, they usually begin soon after the shot and last 2 or 3 days.

Problems that could happen after any vaccine:

Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

Older children, adolescents, and adults might also experience these problems after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5**What if there is a serious reaction?****What should I look for?**

- Look for anything that concerns you, such as signs of a **severe allergic reaction**, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6**The National Vaccine Injury Compensation Program**

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7**How can I learn more?**

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

**Vaccine Information Statement
Hib Vaccine**

4/02/2015

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

HPV (Human Papillomavirus) Vaccine— Gardasil®-9: *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Gardasil-9 prevents human papillomavirus (HPV) types that cause many cancers, including:

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females,
- **anal cancer** in females and males,
- **throat cancer** in females and males, and
- **penile cancer** in males.

In addition, Gardasil-9 prevents HPV types that cause **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cases of cervical cancer.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans, including teens, get infected every year. Most infections will go away and not cause serious problems. But thousands of women and men get cancer and diseases from HPV.

2 HPV vaccine

Gardasil-9 is an FDA-approved HPV vaccine. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years.

Three doses of Gardasil-9 are recommended with the second dose given 1–2 months after the first dose and the third dose given 6 months after the first dose.

3 Some people should not get this vaccine

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.

- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or your baby. Any woman who learns she was pregnant when she got Gardasil-9 vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



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4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get HPV vaccine do not have any serious problems with it.

Mild or moderate problems following Gardasil-9:

- Reactions in the arm where the shot was given:
 - Soreness (about 9 people in 10)
 - Redness or swelling (about 1 person in 3)
- Fever:
 - Mild (100°F) (about 1 person in 10)
 - Moderate (102°F) (about 1 person in 65)
- Other problems:
 - Headache (about 1 person in 3)

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction.

Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/.

5 What if there is a serious reaction?

What should I look for?

Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/hpv

Vaccine Information Statement HPV Vaccine (Gardasil-9)

03/31/2016

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

MMR Vaccine

What You Need to Know

(Measles, Mumps
and Rubella)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Measles, mumps, and rubella are serious diseases. Before vaccines they were very common, especially among children.

Measles

- Measles virus causes rash, cough, runny nose, eye irritation, and fever.
- It can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.

Mumps

- Mumps virus causes fever, headache, muscle pain, loss of appetite, and swollen glands.
- It can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and rarely sterility.

Rubella (German Measles)

- Rubella virus causes rash, arthritis (mostly in women), and mild fever.
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

These diseases spread from person to person through the air. You can easily catch them by being around someone who is already infected.

Measles, mumps, and rubella (MMR) vaccine can protect children (and adults) from all three of these diseases.

Thanks to successful vaccination programs these diseases are much less common in the U.S. than they used to be. But if we stopped vaccinating they would return.

2 Who should get MMR vaccine and when?

Children should get 2 doses of MMR vaccine:

- **First Dose:** 12–15 months of age
- **Second Dose:** 4–6 years of age (may be given earlier, if at least 28 days after the 1st dose)

Some infants younger than 12 months should get a dose of MMR if they are traveling out of the country. (This dose will not count toward their routine series.)

Some adults should also get MMR vaccine: Generally, anyone 18 years of age or older who was born after 1956 should get at least one dose of MMR vaccine, unless they can show that they have either been vaccinated or had all three diseases.

MMR vaccine may be given at the same time as other vaccines.

Children between 1 and 12 years of age can get a “combination” vaccine called MMRV, which contains both MMR and varicella (chickenpox) vaccines. There is a separate Vaccine Information Statement for MMRV.

3 Some people should not get MMR vaccine or should wait.

- Anyone who has ever had a life-threatening allergic reaction to the antibiotic neomycin, or any other component of MMR vaccine, should not get the vaccine. Tell your doctor if you have any severe allergies.
- Anyone who had a life-threatening allergic reaction to a previous dose of MMR or MMRV vaccine should not get another dose.
- Some people who are sick at the time the shot is scheduled may be advised to wait until they recover before getting MMR vaccine.
- Pregnant women should not get MMR vaccine. Pregnant women who need the vaccine should wait until after giving birth. Women should avoid getting pregnant for 4 weeks after vaccination with MMR vaccine.



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- Tell your doctor if the person getting the vaccine:
 - Has HIV/AIDS, or another disease that affects the immune system
 - Is being treated with drugs that affect the immune system, such as steroids
 - Has any kind of cancer
 - Is being treated for cancer with radiation or drugs
 - Has ever had a low platelet count (a blood disorder)
 - Has gotten another vaccine within the past 4 weeks
 - Has recently had a transfusion or received other blood products

Any of these might be a reason to not get the vaccine, or delay vaccination until later.

4 What are the risks from MMR vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions.

The risk of MMR vaccine causing serious harm, or death, is extremely small.

Getting MMR vaccine is much safer than getting measles, mumps or rubella.

Most people who get MMR vaccine do not have any serious problems with it.

Mild problems

- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (about 1 person out of 75)

If these problems occur, it is usually within 6-14 days after the shot. They occur less often after the second dose.

Moderate problems

- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

Severe problems (very rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after a child gets MMR vaccine, including:
 - Deafness
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage

These are so rare that it is hard to tell whether they are caused by the vaccine.

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim) MMR Vaccine

4/20/2012

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Meningococcal ACWY Vaccines—MenACWY and MPSV4: *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Meningococcal disease often occurs without warning—even among people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *N. meningitidis*, called “serogroups.” Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, amputations, nervous system problems, or severe scars from skin grafts.

Meningococcal ACWY vaccines can help prevent meningococcal disease caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available to help protect against serogroup B.

2 Meningococcal ACWY Vaccines

There are two kinds of meningococcal vaccines licensed by the Food and Drug Administration (FDA) for protection against serogroups A, C, W, and Y: meningococcal conjugate vaccine (**MenACWY**) and meningococcal polysaccharide vaccine (**MPSV4**).

Two doses of MenACWY are routinely recommended for adolescents 11 through 18 years old: the first dose at 11 or 12 years old, with a booster dose at age 16. Some adolescents, including those with HIV, should get additional doses. Ask your health care provider for more information.

In addition to routine vaccination for adolescents, MenACWY vaccine is also recommended for certain groups of people:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called “persistent complement component deficiency”
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with isolates of *N. meningitidis*
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa
- College freshmen living in dormitories
- U.S. military recruits

Children between 2 and 23 months old, and people with certain medical conditions need multiple doses for adequate protection. Ask your health care provider about the number and timing of doses, and the need for booster doses.

MenACWY is the preferred vaccine for people in these groups who are 2 months through 55 years old, have received MenACWY previously, or anticipate requiring multiple doses.

MPSV4 is recommended for adults older than 55 who anticipate requiring only a single dose (travelers, or during community outbreaks).



3**Some people should not get this vaccine**

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.**

If you have ever had a life-threatening allergic reaction after a previous dose of meningococcal ACWY vaccine, or if you have a severe allergy to any part of this vaccine, you should not get this vaccine. Your provider can tell you about the vaccine's ingredients.

- **If you are pregnant or breastfeeding.**

There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4**Risks of a vaccine reaction**

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

As many as half of the people who get meningococcal ACWY vaccine have **mild problems** following vaccination, such as redness or soreness where the shot was given. If these problems occur, they usually last for 1 or 2 days. They are more common after MenACWY than after MPSV4.

A small percentage of people who receive the vaccine develop a mild fever.

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5**What if there is a serious reaction?****What should I look for?**

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

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The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7**How can I learn more?**

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

**Vaccine Information Statement
Meningococcal ACWY Vaccines**

03/31/2016

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

Serogroup B Meningococcal Vaccine (MenB): What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

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1 Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Meningococcal disease often occurs without warning—even among people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *N. meningitidis*, called “serogroups.” Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, amputations, nervous system problems, or severe scars from skin grafts.

Serogroup B meningococcal (MenB) vaccines can help prevent meningococcal disease caused by serogroup B. Other meningococcal vaccines are recommended to help protect against serogroups A, C, W, and Y.

2 Serogroup B Meningococcal Vaccines

Two serogroup B meningococcal vaccines—Bexsero® and Trumenba®—have been licensed by the Food and Drug Administration (FDA).

These vaccines are recommended routinely for people 10 years or older who are at increased risk for serogroup B meningococcal infections, including:

- People at risk because of a serogroup B meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called “persistent complement component deficiency”
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with isolates of *N. meningitidis*

These vaccines may also be given to anyone 16 through 23 years old to provide short term protection against most strains of serogroup B meningococcal disease; 16 through 18 years are the preferred ages for vaccination.

For best protection, more than 1 dose of a serogroup B meningococcal vaccine is needed. The same vaccine must be used for all doses. Ask your health care provider about the number and timing of doses.

3 Some people should not get these vaccines

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.**
If you have ever had a life-threatening allergic reaction after a previous dose of serogroup B meningococcal vaccine, or if you have a severe allergy to any part of this vaccine, you should not get the vaccine. *Tell your health care provider if you have any severe allergies that you know of, including a severe allergy to latex.* He or she can tell you about the vaccine’s ingredients.
- **If you are pregnant or breastfeeding.**
There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



U.S. Department of
Health and Human Services
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Control and Prevention

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

More than half of the people who get serogroup B meningococcal vaccine have **mild problems** following vaccination. These reactions can last up to 3 to 7 days, and include:

- Soreness, redness, or swelling where the shot was given
- Tiredness or fatigue
- Headache
- Muscle or joint pain
- Fever or chills
- Nausea or diarrhea

Other problems that could happen after these vaccines:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than the more routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your clinic.

Afterward the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Serogroup B Meningococcal Vaccine

08/09/2016

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

Pneumococcal Conjugate Vaccine (PCV13)

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Vaccination can protect both children and adults from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:

- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis).

Pneumococcal pneumonia is most common among adults. Pneumococcal meningitis can cause deafness and brain damage, and it kills about 1 child in 10 who get it.

Anyone can get pneumococcal disease, but children under 2 years of age and adults 65 years and older, people with certain medical conditions, and cigarette smokers are at the highest risk.

Before there was a vaccine, the United States saw:

- more than 700 cases of meningitis,
- about 13,000 blood infections,
- about 5 million ear infections, and
- about 200 deaths

in children under 5 each year from pneumococcal disease. Since vaccine became available, severe pneumococcal disease in these children has fallen by 88%.

About 18,000 older adults die of pneumococcal disease each year in the United States.

Treatment of pneumococcal infections with penicillin and other drugs is not as effective as it used to be, because some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 PCV13 vaccine

Pneumococcal conjugate vaccine (called PCV13) protects against 13 types of pneumococcal bacteria.

PCV13 is routinely given to children at 2, 4, 6, and 12–15 months of age. It is also recommended for children and adults 2 to 64 years of age with certain health conditions, and for all adults 65 years of age and older. Your doctor can give you details.

3 Some people should not get this vaccine

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine. *Tell your doctor if the person being vaccinated has any severe allergies.*

If the person scheduled for vaccination is not feeling well, your healthcare provider might decide to reschedule the shot on another day.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Problems reported following PCV13 varied by age and dose in the series. The most common problems reported among children were:

- About half became drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a fever over 102.2°F.
- Up to about 8 out of 10 became fussy or irritable.

Adults have reported pain, redness, and swelling where the shot was given; also mild fever, fatigue, headache, chills, or muscle pain.

Young children who get PCV13 along with inactivated flu vaccine at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some older children and adults get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very small chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5

What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.

Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7

How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement
PCV13 Vaccine

11/05/2015

42 U.S.C. § 300aa-26

Office Use Only



Polio Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Vaccination can protect people from **polio**. Polio is a disease caused by a virus. It is spread mainly by person-to-person contact. It can also be spread by consuming food or drinks that are contaminated with the feces of an infected person.

Most people infected with polio have no symptoms, and many recover without complications. But sometimes people who get polio develop paralysis (cannot move their arms or legs). Polio can result in permanent disability. Polio can also cause death, usually by paralyzing the muscles used for breathing.

Polio used to be very common in the United States. It paralyzed and killed thousands of people every year before polio vaccine was introduced in 1955. There is no cure for polio infection, but it can be prevented by vaccination.

Polio has been eliminated from the United States. But it still occurs in other parts of the world. It would only take one person infected with polio coming from another country to bring the disease back here if we were not protected by vaccination. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

2 Polio vaccine

Inactivated Polio Vaccine (**IPV**) can prevent polio.

Children

Most people should get IPV when they are children. Doses of IPV are usually given at 2, 4, 6 to 18 months, and 4 to 6 years of age.

The schedule might be different for some children (including those traveling to certain countries and those who receive IPV as part of a combination vaccine). Your health care provider can give you more information.

Adults

Most adults do not need IPV because they were already vaccinated against polio as children. But some adults are at higher risk and should consider polio vaccination, including:

- people traveling to certain parts of the world,
- laboratory workers who might handle polio virus, and
- health care workers treating patients who could have polio.

These higher-risk adults may need 1 to 3 doses of IPV, depending on how many doses they have had in the past.

There are no known risks to getting IPV at the same time as other vaccines.

3 Some people should not get this vaccine

Tell the person who is giving the vaccine:

- **If the person getting the vaccine has any severe, life-threatening allergies.**

If you ever had a life-threatening allergic reaction after a dose of IPV, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.

- **If the person getting the vaccine is not feeling well.**

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Some people who get IPV get a sore spot where the shot was given. IPV has not been known to cause serious problems, and most people do not have any problems with it.



Other problems that could happen after this vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than the more routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious problem?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your clinic.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Polio Vaccine

7/20/2016

42 U.S.C. § 300aa-26

Office Use Only



Rotavirus Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Rotavirus is a virus that causes diarrhea, mostly in babies and young children. The diarrhea can be severe, and lead to dehydration. Vomiting and fever are also common in babies with rotavirus.

Before rotavirus vaccine, rotavirus disease was a common and serious health problem for children in the United States. Almost all children in the United States had at least one rotavirus infection before their 5th birthday.

Every year before the vaccine was available:

- more than 400,000 young children had to see a doctor for illness caused by rotavirus,
- more than 200,000 had to go to the emergency room,
- 55,000 to 70,000 had to be hospitalized, and
- 20 to 60 died.

Since the introduction of the rotavirus vaccine, hospitalizations and emergency visits for rotavirus have dropped dramatically.

2 Rotavirus vaccine

Two brands of rotavirus vaccine are available. Your baby will get either 2 or 3 doses, depending on which vaccine is used.

Doses are recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed)

Your child must get the first dose of rotavirus vaccine before 15 weeks of age, and the last by age 8 months. Rotavirus vaccine may safely be given at the same time as other vaccines.

Almost all babies who get rotavirus vaccine will be protected from severe rotavirus diarrhea. And most of these babies will not get rotavirus diarrhea at all.

The vaccine will not prevent diarrhea or vomiting caused by other germs.

Another virus called porcine circovirus (or parts of it) can be found in both rotavirus vaccines. This is not a virus that infects people, and there is no known safety risk. For more information, see www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.htm.

3 Some babies should not get this vaccine

A baby who has had a life-threatening allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe allergy to any part of rotavirus vaccine should not get the vaccine. *Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.*

Babies with “severe combined immunodeficiency” (SCID) should not get rotavirus vaccine.

Babies who have had a type of bowel blockage called “intussusception” should not get rotavirus vaccine.

Babies who are mildly ill can get the vaccine. Babies who are moderately or severely ill should wait until they recover. This includes babies with moderate or severe diarrhea or vomiting.

Check with your doctor if your baby’s immune system is weakened because of:

- HIV/AIDS, or any other disease that affects the immune system
- ~~treatment with drugs such as steroids~~
- cancer, or cancer treatment with x-rays or drugs

4 Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own. Serious side effects are also possible but are rare.

Most babies who get rotavirus vaccine do not have any problems with it. But some problems have been associated with rotavirus vaccine:

Mild problems following rotavirus vaccine:

- Babies might become irritable, or have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine.



Serious problems following rotavirus vaccine:

- Intussusception is a type of bowel blockage that is treated in a hospital, and could require surgery. It happens “naturally” in some babies every year in the United States, and usually there is no known reason for it.

There is also a small risk of intussusception from rotavirus vaccination, usually within a week after the 1st or 2nd vaccine dose. This additional risk is estimated to range from about 1 in 20,000 to 1 in 100,000 US infants who get rotavirus vaccine. Your doctor can give you more information.

Problems that could happen after any vaccine:

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and usually happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious problem?

What should I look for?

For **intussusception**, look for signs of stomach pain along with severe crying. Early on, these episodes could last just a few minutes and come and go several times in an hour. Babies might pull their legs up to their chest.

Your baby might also vomit several times or have blood in the stool, or could appear weak or very irritable. These signs would usually happen during the first week after the 1st or 2nd dose of rotavirus vaccine, but look for them any time after vaccination.

Look for anything else that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, or unusual sleepiness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is **intussusception**, call a doctor right away. If you can't reach your doctor, take your baby to a hospital. Tell them when your baby got the rotavirus vaccine.

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get your baby to the nearest hospital.

Otherwise, call your doctor.

Afterward, the reaction should be reported to the “Vaccine Adverse Event Reporting System” (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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7 How can I learn more?

- Ask your doctor. Your healthcare provider can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Rotavirus Vaccine

04/15/2015

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

Tdap Vaccine

What You Need to Know

(Tetanus,
Diphtheria and
Pertussis)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Tetanus, diphtheria and pertussis are very serious diseases. Tdap vaccine can protect us from these diseases. And, Tdap vaccine given to pregnant women can protect newborn babies against pertussis..

TETANUS (Lockjaw) is rare in the United States today. It causes painful muscle tightening and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 10 people who are infected even after receiving the best medical care.

DIPHTHERIA is also rare in the United States today. It can cause a thick coating to form in the back of the throat.

- It can lead to breathing problems, heart failure, paralysis, and death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.

- It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.

These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through secretions from coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.

Before vaccines, as many as 200,000 cases of diphtheria, 200,000 cases of pertussis, and hundreds of cases of tetanus, were reported in the United States each year. Since vaccination began, reports of cases for tetanus and diphtheria have dropped by about 99% and for pertussis by about 80%.

2 Tdap vaccine

Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did *not* get Tdap at that age should get it as soon as possible.

Tdap is especially important for healthcare professionals and anyone having close contact with a baby younger than 12 months.

Pregnant women should get a dose of Tdap during **every pregnancy**, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

Another vaccine, called Td, protects against tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have never gotten Tdap before. Tdap may also be given after a severe cut or burn to prevent tetanus infection.

Your doctor or the person giving you the vaccine can give you more information.

Tdap may safely be given at the same time as other vaccines.

3 Some people should not get this vaccine

- A person who has ever had a life-threatening allergic reaction after a previous dose of any diphtheria, tetanus or pertussis containing vaccine, OR has a severe allergy to any part of this vaccine, should not get Tdap vaccine. Tell the person giving the vaccine about any severe allergies.
- Anyone who had coma or long repeated seizures within 7 days after a childhood dose of DTP or DTaP, or a previous dose of Tdap, should not get Tdap, unless a cause other than the vaccine was found. They can still get Td.
- Talk to your doctor if you:
 - have seizures or another nervous system problem,
 - had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
 - ever had a condition called Guillain-Barré Syndrome (GBS),
 - aren't feeling well on the day the shot is scheduled.



U.S. Department of
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Centers for Disease
Control and Prevention

4 Risks

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare.

Most people who get Tdap vaccine do not have any problems with it.

Mild problems following Tdap *(Did not interfere with activities)*

- Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, sore joints (about 1 person in 10)
- Body aches (about 1 person in 3 or 4)
- Rash, swollen glands (uncommon)

Moderate problems following Tdap *(Interfered with activities, but did not require medical attention)*

- Pain where the shot was given (up to 1 in 5 or 6)
- Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 12 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 1 in 7 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 1 in 500).

Severe problems following Tdap *(Unable to perform usual activities; required medical attention)*

- Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare).

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious problem?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.
- Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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7 How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Tdap Vaccine

2/24/2015

42 U.S.C. § 300aa-26



VACCINE INFORMATION STATEMENT

Chickenpox Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Chickenpox (also called varicella) is a common childhood disease. It is usually mild, but it can be serious, especially in young infants and adults.

- It causes a rash, itching, fever, and tiredness.
- It can lead to severe skin infection, scars, pneumonia, brain damage, or death.
- The chickenpox virus can be spread from person to person through the air, or by contact with fluid from chickenpox blisters.
- A person who has had chickenpox can get a painful rash called shingles years later.
- Before the vaccine, about 11,000 people were hospitalized for chickenpox each year in the United States.
- Before the vaccine, about 100 people died each year as a result of chickenpox in the United States.

Chickenpox vaccine can prevent chickenpox.

Most people who get chickenpox vaccine will not get chickenpox. But if someone who has been vaccinated does get chickenpox, it is usually very mild. They will have fewer blisters, are less likely to have a fever, and will recover faster.

2 Who should get chickenpox vaccine and when?

Routine

Children who have never had chickenpox should get 2 doses of chickenpox vaccine at these ages:

- | | |
|-----------|--|
| 1st Dose: | 12–15 months of age |
| 2nd Dose: | 4–6 years of age (may be given earlier, if at least 3 months after the 1st dose) |

People 13 years of age and older (who have never had chickenpox or received chickenpox vaccine) should get two doses at least 28 days apart.

Catch-up

Anyone who is not fully vaccinated, and never had chickenpox, should receive one or two doses of chickenpox vaccine. The timing of these doses depends on the person's age. Ask your doctor.

Chickenpox vaccine may be given at the same time as other vaccines.

Note: A "combination" vaccine called **MMRV**, which contains both chickenpox and MMR vaccines, may be given instead of the two individual vaccines to people 12 years of age and younger.

3 Some people should not get chickenpox vaccine or should wait.

- People should not get chickenpox vaccine if they have ever had a life-threatening allergic reaction to a previous dose of chickenpox vaccine or to gelatin or the antibiotic neomycin.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting chickenpox vaccine.
- Pregnant women should wait to get chickenpox vaccine until after they have given birth. Women should not get pregnant for 1 month after getting chickenpox vaccine.
- Some people should check with their doctor about whether they should get chickenpox vaccine, including anyone who:
 - Has HIV/AIDS or another disease that affects the immune system
 - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer
 - Has any kind of cancer
 - Is getting cancer treatment with radiation or drugs
- People who recently had a transfusion or were given other blood products should ask their doctor when they may get chickenpox vaccine.

Ask your doctor for more information.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

4**What are the risks from chickenpox vaccine?**

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of chickenpox vaccine causing serious harm, or death, is extremely small.

Getting chickenpox vaccine is much safer than getting chickenpox disease. Most people who get chickenpox vaccine do not have any problems with it. Reactions are usually more likely after the first dose than after the second.

Mild problems

- Soreness or swelling where the shot was given (about 1 out of 5 children and up to 1 out of 3 adolescents and adults)
- Fever (1 person out of 10, or less)
- Mild rash, up to a month after vaccination (1 person out of 25). It is possible for these people to infect other members of their household, but this is extremely rare.

Moderate problems

- Seizure (jerking or staring) caused by fever (very rare).

Severe problems

- Pneumonia (very rare)

Other serious problems, including severe brain reactions and low blood count, have been reported after chickenpox vaccination. These happen so rarely experts cannot tell whether they are caused by the vaccine or not. If they are, it is extremely rare.

Note: The first dose of **MMRV** vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5.

Seizures caused by a fever are also reported more often after MMRV. These usually occur 5–12 days after the first dose.

5**What if there is a serious reaction?****What should I look for?**

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

6**The National Vaccine Injury Compensation Program**

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

7**How can I learn more?**

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
Varicella Vaccine

3/13/2008

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